Notice of Allowability	Application No.	Applicant(s)	
	10/722,253	SAY ET AL.	
	Examiner	Art Unit	
	Navin Natnithithadha	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *24 June 2005*.

2. ☒ The allowed claim(s) is/are *1-20*.

3. ☒ The drawings filed on *24 November 2003* are accepted by the Examiner.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Kuni Oh on 24 June 2005.

Please amend claim 1 with the following:

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1. (Currently amended) A method of detecting failures in an implanted analyte-responsive sensor, the method comprising:

implanting an analyte-responsive sensor into a patient, the analyte-responsive sensor comprising N working electrodes, where N is an integer and is two or greater, and a common counter electrode;

obtaining a signal generated at one of the N working electrodes and a signal generated at the common counter electrode; and

determining failure of the analyte-responsive sensor if the signal from the common counter electrode is not N times the signal from the one of the N working electrodes~~, within a predetermined threshold limit~~.

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Please add the following new claims:

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2. (New) The method of claim 1 wherein the determining step includes the step of comparing the signal generated at the one of the N working electrodes with the signal generated at the common counter electrode.

3. (New) The method of claim 2 wherein the comparing step is initiated by the patient.

4. (New) The method of claim 1 wherein the analyte-responsive sensor includes a glucose sensor.

5. (New) The method of claim 1 further including the step of alerting the patient if the failure of the analyte-responsive sensor is determined.

6. (New) The method of claim 5 wherein the step of alerting the patient includes the step of outputting one or more of an audio alert, a visual alert or a vibratory alert.

7. (New) The method of claim 1 further including the steps of:

replacing the analyte-responsive sensor implanted in the patient with another analyte-responsive sensor when failure of the sensor is determined.

8. (New) The method of claim 7 further including the step of calibrating the another analyte-responsive sensor.

9. (New) The method of claim 7 further including the step of alerting the patient to calibrate the another analyte-responsive sensor when a predetermined time interval has passed after the implantation of the another analyte-responsive sensor and calibration has not been performed.

10. (New) The method of claim 9 wherein the step of alerting the patient includes the step of outputting one or more of an audio alert, a visual alert, or a vibratory alert.

11. (New) The method of claim 1 further including the steps of:
generating a respective signal at each of the N working electrodes; and
comparing the respective generated signals to determine whether the generated respective signals are substantially within a predetermined level of tolerance.

12. (New) The method of claim 11, further including the step of alerting the patient to replace the analyte-responsive sensor when the generated respective signals are not substantially within the predetermined level of tolerance.

13. (New) The method of claim 11, further including the step of alerting the patient to replace the analyte-responsive sensor when the generated respective signals are not substantially in agreement for a predetermined period of time.

14. (New) The method of claim 11 wherein the comparing step is performed at a predetermined time interval.

15. (New) The method of claim 11 wherein the comparing step is initiated by the patient.

16. (New) The method of claim 1 wherein the analyte-responsive sensor includes a subcutaneous sensor.

17. (New) The method of claim 16 wherein the subcutaneous sensor includes a glucose sensor.

18. (New) The method of claim 1 further including the step of calibrating the analyte-responsive sensor.

19. (New) The method of claim 18 wherein the calibrating step includes the steps of:

generating a signal from each of the N working electrodes;

determining if the generated signals from the respective N working electrodes differ by substantially less than a first threshold level; and

determining if the generated signals from the respective N working electrodes are within a predetermined range; and

determining if a rate of change of the each respective signal from the corresponding one of the N working electrodes is less than a second threshold level.

20. (New) The method of claim 18 wherein the calibrating step further includes the steps of:

assaying a calibration sample of the patient's body fluid to determine a calibration value; and

relating the calibration value to the at least one of the signals from the N working electrodes when the determining steps are satisfied.

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REASONS FOR ALLOWANCE

2. The following is an examiner's statement of reasons for allowance:

As to independent claim 1, the prior art does not teach a method of detecting failures in an implanted analyte sensor, comprising: determining failure of the analyte sensor if the signal from the counter electrode is not N times the signal from the one of the N working electrodes.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Navin Natnithithadha whose telephone number is (571) 272-4732. The examiner can normally be reached on Monday-Friday, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Navin Natnithithadha
Patent Examiner
GAU 3736
27 June 2005

ROBERT L. NASSER
PRIMARY EXAMINER